

What is Claimed:

1. A pharmaceutical composition comprising as an active ingredient a therapeutically effective amount of Copolymer 5 (glatiramer acetate), and microcrystalline cellulose.
2. The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is at least 50 % by weight.
- 10 3. The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is at least 70 % by weight.
- 15 4. The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is from about 60% to about 90% by weight.
- 20 5. The pharmaceutical composition of claim 1, wherein the amount of microcrystalline cellulose is from about 70% to about 80% by weight.
- 25 6. The pharmaceutical composition of claim 1, wherein the microcrystalline cellulose has a moisture content of up to 5.0%.
- 30 7. The pharmaceutical composition of claim 1, wherein the microcrystalline cellulose has a moisture content of up to 1.5%.
8. The pharmaceutical composition of claim 1, further comprising a disintegrant.
- 35 9. The pharmaceutical composition of claim 8, wherein the disintegrant is selected from the group consisting of

kaolin, starch, powdered sugar, sodium starch glycolate, crosscarmelose sodium, carboxymethyl cellulose, microcrystalline cellulose and sodium alginate.

5      10. The pharmaceutical composition of claim 9, wherein the disintegrant is a pregelatinized starch.

10      11. The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 14%.

12. The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 12%.

15      13. The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 7%.

14. The pharmaceutical composition of claim 10, wherein the starch has a moisture content of up to 5%.

20      15. The pharmaceutical composition of claim 1, further comprising a lubricant.

25      16. The pharmaceutical composition of claim 15, wherein the lubricant is selected from the group consisting of talc, sodium stearyl fumarate, magnesium stearate, calcium stearate, hydrogenated castor oil, hydrogenated soybean oil, and polyethylene glycol.

30      17. The pharmaceutical composition of claim 16, wherein the lubricant is magnesium stearate.

18. The pharmaceutical composition of claim 1, further comprising an enteric coating.

19. The pharmaceutical composition of claim 1, wherein the enteric coating is methacrylic acid copolymer.

5       20. The pharmaceutical composition of claim 18, wherein the enteric coating is selected from the group consisting of cellulose acetate phthalate (CAP), hydroxypropyl methyl cellulose phthalate (HPMCP), carboxymethyl ethyl cellulose (CMEC), or amino-alkylmethacrylate copolymer.

10      21. The pharmaceutical composition of claim 1, further comprising a film coating under the enteric coating.

15      22. The pharmaceutical composition of claim 21, wherein the film coating is selected from the group consisting of hydroxy propyl methyl cellulose (HPMC) and poly vinyl alcohol (PVA).

23. The pharmaceutical composition of claim 1 in solid form.

20      24. The pharmaceutical composition of claim 23, wherein the solid form is selected from the group consisting of a tablet, a hard gelatin capsule, a pellet and a particulate formulation.

25      25. The pharmaceutical composition of claim 24, wherein the solid form is a tablet and the effective amount of Copolymer 1 (glatiramer acetate) is from about 0.1 mg to about 300 mg.

30      26. The pharmaceutical composition of claim 25, wherein the effective amount of Copolymer 1 (glatiramer acetate) is from about 5 mg to about 100 mg.

27. The pharmaceutical composition of claim 25, wherein the effective amount of Copolymer 1 (glatiramer acetate) is about 5 mg.

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28. The pharmaceutical composition of claim 25, wherein the effective amount of Copolymer 1 (glatiramer acetate) is about 50 mg.

10 29. A pharmaceutical composition in solid form comprising as an active ingredient a therapeutically effective amount of Copolymer 1 (glatiramer acetate), 70%-80% by weight of microcrystalline cellulose, and an enteric coating.

15 30. The pharmaceutical composition of claim 29, wherein the effective amount of Copolymer 1 (glatiramer acetate) is about 5 mg.

20 31. The pharmaceutical composition of claim 29, wherein the effective amount of Copolymer 1 (glatiramer acetate) is about 50 mg.

25 32. The pharmaceutical composition of claim 1, further comprising a pharmaceutically acceptable carrier suitable for application to mucosal linings, so as to thereby form a composition suitable for application to the mucosal linings of a subject.

30 33. The pharmaceutical composition of claim 32, wherein the carrier is chitosan.

34. The pharmaceutical composition of claim 33, further comprising a pharmaceutically effective amount of an anti-microbial preservative.

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35. The pharmaceutical composition of claim 34, wherein the anti-microbial preservative is selected from the group consisting of sodium benzoate, methyl paraben, benzalkonium chloride, and propyl paraben.

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36. The pharmaceutical composition of claim 32, in aqueous form.

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37. The pharmaceutical composition of claim 32, in dry powder form.

38. The pharmaceutical composition of claim 32, wherein the mucosal linings are bronchi-associated lymphoid tissue.

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39. The pharmaceutical composition of claim 32, formulated for oral administration.

40. The pharmaceutical composition of claim 32, formulated for nasal administration.

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41. The pharmaceutical composition of claim 32, formulated for pulmonary administration.

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42. The pharmaceutical composition of claim 32, formulated for buccal administration.

43. A process for manufacturing the composition of claim 1, comprising:

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a) milling the Copolymer 1 (glatiramer acetate),  
b) dry mixing the milled Copolymer 1 (glatiramer acetate) with at least 50% by weight of microcrystalline cellulose.

44. The process of claim 43, further comprising applying a film coating.

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45. The process of claim 43, further comprising applying an enteric coating.

46. The process of claim 45, wherein the enteric coating is applied using a rotating pan system.

47. A method for treating an autoimmune disease in a mammal which comprises administering to the mammal the composition of claim 1.

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48. The method of claim 47, wherein said autoimmune disease is multiple sclerosis.

49. The method of claim 47, wherein said autoimmune disease is selected from the group consisting of an arthritic condition, autoimmune hemolytic anemia, autoimmune oophoritis, autoimmune uveoretinitis, Crohn's disease, chronic immune thrombocytopenic purpura, colitis, contact sensitivity disease, Graves disease, Guillain-Barre's syndrome, Hashimoto's disease, idiopathic myxedema, myasthenia gravis, psoriasis, pemphigus vulgaris, rheumatoid arthritis, GVHD and HVGD.

50. The pharmaceutical composition of claim 29, wherein the effective amount of Copolymer 1 (glatiramer acetate) is from about 5 mg to about 100 mg.

51. The pharmaceutical composition of claim 29, wherein the effective amount of Copolymer 1 (glatiramer acetate) is about 5 mg.

52. The pharmaceutical composition of claim 29, wherein the effective amount of Copolymer 1 (glatiramer acetate) is about 50 mg.

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53. The pharmaceutical composition of claim 29, wherein the effective amount of Copolymer 1 (glatiramer acetate) is from about 0.01 mg/kg to about 2 mg/kg.

5 54. The pharmaceutical composition of claim 29, wherein the effective amount of Copolymer 1 (glatiramer acetate) is from about 0.05 mg/kg to about 1 mg/kg.

10 55. A method for treating an autoimmune disease in a mammal which comprises administering to the mammal the composition of claim 50.

15 56. The method of claim 54, wherein said autoimmune disease is multiple sclerosis.

20 57. The method of claim 54, wherein said autoimmune disease is selected from the group consisting of an arthritic condition, autoimmune hemolytic anemia, autoimmune oophoritis, autoimmune uveoretinitis, Crohn's disease, chronic immune thrombocytopenic purpura, colitis, contact sensitivity disease, Graves disease, Guillain-Barre's syndrome, Hashimoto's disease, idiopathic myxedema, myasthenia gravis, psoriasis, pemphigus vulgaris, rheumatoid arthritis, GVHD and HVGD.

25 58. A method for treating an autoimmune disease in a mammal which comprises administering to the mammal the composition of claim 53.

30 59. The method of claim 57, wherein said autoimmune disease is multiple sclerosis.

35 60. The method of claim 57, wherein said autoimmune disease is selected from the group consisting of an arthritic condition, autoimmune hemolytic anemia, autoimmune oophoritis, autoimmune uveoretinitis, Crohn's disease,

chronic immune thrombocytopenic purpura, colitis, contact sensitivity disease, Graves disease, Guillain-Barre's syndrome, Hashimoto's disease, idiopathic myxedema, myasthenia gravis, psoriasis, pemphigus vulgaris,  
5 rheumatoid arthritis, GVHD and HVGD.

61. The pharmaceutical composition of claim 1, further comprising a protease inhibitor.